Site visit inspection report on compliance with HTA minimum standards

Ashford and St Peter's Hospitals NHS Foundation Trust

HTA licensing number 12542

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

30 July 2015

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Ashford and St Peter's Hospital NHS Foundation Trust (the establishment) had met the majority of the HTA standards, two minor shortfalls were identified in relation to governance and quality systems. These related to licensed activity taking place within the Maternity Department and identification procedures in the mortuary.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The Ashford and St Peter's Hospitals NHS Foundation Trust is one of three Trusts which together form Surrey Pathology Services. The mortuary conducts both adult hospital and coronial post-mortem (PM) examinations, and has recently started performing Home Office PM examinations. The establishment conducts approximately 800 PM examinations each year on behalf of HM Coroner for Surrey, for which authorisation is received from the Coroner's Office by fax. Trained staff seek consent for adult hospital PM examinations, of which there are approximately two performed annually. Trained members of staff also seek consent for perinatal and paediatric PM examinations; however these are performed at another HTA licensed establishment.

Bodies are received into the mortuary from the community and from wards within the hospital during and outside of normal working hours. Following a hospital death, the deceased is transported on a concealment trolley to the mortuary by trained portering staff, who complete the mortuary admission form and place the body into refrigerated storage. Bodies of the deceased from within the community are transported to the mortuary by the Coroner's approved funeral directors. Outside of normal working hours, access to the mortuary is granted by security staff, who remain present to ensure that security is maintained. The funeral directors are responsible for completing the necessary documentation and placing the body into refrigerated storage.

Mortuary staff perform daily checks of new admissions to the mortuary and are responsible for checking the bodies of the deceased, confirming identification, and completing the mortuary register for each body received.

Bodies are only released from the establishment by mortuary staff, and there are procedures in place to ensure that release outside of normal working hours only takes place in the presence of the on-call member of mortuary staff.

Viewings are generally conducted by prior arrangement during normal working hours and are carried out by mortuary staff. In extenuating circumstances, viewings may be conducted outside of normal hours, in which case a member of the on-call staff and security attend.

The mortuary comprises a single PM suite incorporating three height-adjustable down draft tables, one of which is designed specifically for bariatric cases.

The establishment has the capacity to store 85 bodies in monitored and alarmed fridges, of which six spaces are reserved for perinatal/paediatric cases and 20 spaces are capable of storing bariatric cases. A separate refrigerated room is available, which can be configured to store the bodies of larger bariatric cases. A dedicated fridge is also available within the Maternity Department for short-term storage prior to transport to the mortuary. Ten adult freezer spaces are available for the storage of long-term cases. The establishment has contingency arrangements in place, including use of another location within the Trust with the capacity to store an additional 30 bodies. Bodies are only stored at this site prior to release to funeral directors (see Advice, item 6).

Tissue removed during PM examination is recorded on the PM examination form and transported to another HTA licensed establishment for processing. Tissue blocks and slides are returned to the establishment post processing and are stored securely within the Histology Department, which is accredited by CPA (UK) Ltd. Traceability of blocks and slides is maintained via paper and electronic records.

This was the third inspection of the establishment, which has been licensed since 2009. Previous inspections were conducted in 2009 and 2012 from which there were no outstanding shortfalls or conditions against the licence.

The inspection included a review of documentation relevant to the establishment's activities, a visual inspection of the Mortuary, Histology and Maternity Departments, and interviews with key members of staff including: the Designated Individual (DI) who is a Consultant Histopathologist; the Mortuary Services Manager/Lead BMS; a Senior and Trainee Anatomical Pathology Technologist; an Associate Practitioner for Histology and a member of staff from the Bereavement Office.

A traceability audit was conducted on two bodies - one hospital death and one coronial case. The following information, where applicable, was cross referenced with the body admission form and mortuary register: the deceased's name; date of birth; date received into the mortuary; location from where the body was received; hospital number; NHS number; unique mortuary number; and fridge storage location.

In addition, an audit was conducted of the records and paraffin embedded tissue blocks and slides relating to two post mortem cases. The following information was cross referenced, where applicable: name; unique post mortem number; the number of blocks produced; and instructions for retention or disposal. Traceability was maintained throughout and no discrepancies were identified in the accompanying documentation.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	There is currently no standard operating procedure setting out refrigerated storage arrangements within the Maternity Department. There is also no documented evidence that staff have received training regarding the procedures associated with the use of this fridge, for example, labelling and traceability requirements and alarm response procedures.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Bodies of the deceased are assigned a unique mortuary number by establishment staff. However, whilst this number is recorded in the mortuary register, bodies are not labelled with this unique identifier (See Advice, item 5). In addition the Hospital Release Form only includes the name of the deceased, it does not incorporate any other unique identifier (See Advice, item 3).	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ 1	The establishment has a range of meetings covering licensed activities, including a quarterly HTA meeting. The DI is advised to extend invitations for this meeting to the Bereavement Office and Maternity staff. This will ensure that meetings include representation from all areas involved in these activities.
2.	GQ 1	The SOP governing identification procedures states that a red label will be placed in the mortuary register to identify bodies of deceased with similar/same names. In practice this is no longer performed, as the labels were found unsuitable. The DI is advised to review the SOP to ensure that it reflects current practice. Whilst attention is bought to same/similar names in the register by the use of asterisks, and staff place a red wrist band on the deceased, the DI may wish to consider additional methods of identification such as the use of a coloured magnetic disc affixed to the fridge door.

3.	GQ 1	Mortuary staff require a completed Hospital Release Form from the Bereavement Office before facilitating the release of a body to a funeral director. Whilst this form includes the name of the deceased and the collecting funeral director, it does not include a unique identifier. The DI is advised to include as minimum the date of birth, hospital number or NHS number. This will help mitigate the risk of releasing the wrong body, particularly in the instance of a 'same name' scenario.
4.	GQ 3	Under the current arrangement within the Surrey Pathology Service, staff may be required to cover for staff at other licensed establishments. Considering the steady increase in PM activity recorded at the establishment, the DI should risk assess staffing levels within the mortuary and ensure that this arrangement does not have a detrimental affect upon its ability to conduct licensed activities.
5.	GQ 6	The DI should consider implementing a procedure whereby an additional wrist bracelet is attached to the deceased which states the unique mortuary number, and to update the associated SOP to reflect this change. In a 'same name' scenario, and in the absence of other identifiers such as date of birth, this unique mortuary number is of paramount importance.
6.	PFE 3	The site visit inspection did not include the off site contingency storage; however the DI is advised to ensure that standards are aligned between both facilities.
7.	PFE 3	Following the review of audit findings, HTA compliance information and discussion with staff, it became evident that the establishment has become reliant upon offsite contingency arrangements and emergency body storage solutions during periods of increased activity. The inspection team was informed that a case has been submitted for the purchase of two emergency body storage units; however the establishment is reminded that these units are not intended to be used for long term storage. The DI and establishment are advised to consider a long term solution to capacity concerns.
8.	PFE 3	There is a 24-hour alarm monitoring system in place for mortuary fridges and freezers; however this system is not subject to routine testing. The DI is advised to test the alarm system periodically to confirm that the alarm and the associated procedures function as expected. This is particularly important with regards to the fridge in maternity, since although the unit is staffed 24 hours per day the fridge is only fitted with a local alarm and not incorporated into the 24 hour alarm monitoring system.
9.	PFE 5	Maintenance records and service reports for environmental monitoring such as PM room airflow are currently retained by the Estates Department. To facilitate early identification of potential problems, the DI is advised to ensure that copies of these records are provided to the mortuary staff.
10.	N/A	The DI is advised to identify a suitable Person(s) Designated within the Maternity Department to assist in the local governance of licensed activities.

Concluding comments

The HTA observed a number of strengths and areas of good practice during the inspection. The establishment is managed by a dedicated and experienced team, and it was evident through discussion that respect and dignity of the deceased are of high importance.

The establishment also demonstrated a commitment to continuous improvement by addressing the advice and guidance provided at the previous HTA inspection. The quality management system includes a good range of vertical and horizontal audits, in addition to examination audits to assess both the suitability of the standard operating procedure being assessed and the competency of the staff performing the procedure.

The establishment's quarterly HTA governance meeting includes attendance by a representative from the Coroner's Office to facilitate improved communication on matters regarding cases under Coronial authority.

There are some areas of practice that may benefit from further improvement and the HTA has given advice and guidance to the DI with respect to these.

The HTA requires that the Designated Individual address the two minor shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 14 August 2015

Report returned from DI: 03 September 2015

Final report issued: 09 September 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 30 November 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

(Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
    - fridges / Freezers
    - hydraulic trolleys
    - post mortem tables
    - hoists
    - saws (manual and/or oscillating)
    - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.